

50 MAY 29 11:00:58

Docket No. 11823-9

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )  
 Cary L. Queen et al. )  
 Serial No.: 07/310,252 )  
 Filed: February 13, 1989 )  
 For: DESIGNING IMPROVED )  
 HUMANIZED IMMUNOGLOBULINS )

INFORMATION DISCLOSURE  
 STATEMENT UNDER  
 37 CFR 1.97 AND 1.98

Hon. Commissioner of Patents  
 and Trademarks  
 Washington, D.C. 20231

Sir:

The following references cited on attached form PTO-1449 are being called to the attention of the Examiner. A copy of each is enclosed. It is requested that the Examiner make them of record.

No.	Patent #	Patent Date	Patentee
AA	4,816,397	3/28/89	Boss et al.
AB	4,816,567	3/28/89	Cabilly et al.

No.	Publication No.	Publication Date	Country
AC	0,239,400	9/30/87	EPO
AD	0,173,494	3/5/86	EPO
AE	0,184,187	6/11/86	EPO
AF	WO89/01783	3/9/89	PCT
AG	WO86/5513	9/25/86	PCT
AH	WO87/02671	5/7/87	PCT
AI	0,171,496	2/19/86	EPO
AJ	0,266,663	6/11/88	EPO
AK	2,188,941	10/14/87	GB

No.	Author, Name of Publication, Pages, Dates
A1	Vitteta et al., Science 238:1098-1104 (1987).
A2	Ellison et al., Nucleic Acids Res. 10:4071- (1982).

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- A3 Hieter et al., Cell 22:197-207 (1980).
- A4 Sharon et al., Nature 309:364-367 (1984).
- A5 Takeda et al., Nature 314:452-454 (1985).
- A6 Tan et al., J. Immunol. 135:3564-3567 (1985).
- A7 Morrison et al., Proc. Natl. Acad. Sci. 81:6851-6859 (1984).
- A8 Boulianne et al., Nature 312:643-646 (1984).
- A9 Neuberger et al., Nature 314:268-270 (1985).
- A10 Morrison, S.L., Science 229:1202-1207 (1985).
- A11 Sahagan et al., J. Immunol. 137:1066-1074 (1986).
- A12 Liu et al., Gene 54:33-40 (1987).
- A13 Better et al., Science 240:1041-1043 (1988).
- A14 Waldmann, T.A., Science 232:727-732 (1986).
- A15 Leonard et al., J. Biol. Chem. 260:1872-1880 (1985).
- A16 Uchiyama et al., J. Immunol. 126:1393-1397 (1981).
- A17 Farrar, J., Immunol. Rev. 63:129- 166 (1982).
- A18 Greene et al., in Progress in Hematology XIV, E. Brown, ed., Grune and Statton, New York (1986) p.283-301.
- A19 Verhoyen et al., Science 239:1534-1536 (1988).
- A20 Jones et al., Nature 321:522-525 (1986).
- A21 Hale et al., Lancet December 17, 1988, pp. 1394-1399.
- A22 Chothia, C. and A.M. Lesk, J. Mol. Biol. 196:901-917 (1987).
- A23 Reichmann et al., Nature 332:323-327 (1988).
- A24 Bird et al., Science 242:423-426 (1988).
- A25 Huston et al., Proc. Natl. Acad. Sci. U.S.A. 85:5879-5883 (1988).in Progress in Hematology XIV, E. Brown, ed., Grune and Statton, New York (1986) p.283.

The above documents are considered pertinent for the following reasons:

References A14, A15, A16, A17 and A18 describe IL-2 and IL-2 receptors and antibodies thereto, including anti-Tac antibody, the humanization of which is an example in the present application.

References A2, A3, A12 and A22 describe structural aspects of immunoglobulins.

References AA, AB, AD, AE, AG, AH, AI, AJ, A4, A5, A6,

A7, A8, A9, A10, A11, A13, A19, A24 and A25 generally describe recombinant immunoglobulins, particularly chimeric immunoglobulins.

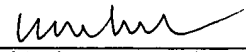
Reference AK describes monoclonal antibodies to IL-2 receptors and also mentions chimeric antibodies, e.g., at page 2, lines 21-27.

References AC, AF, A20, A21 and A23 describe production and use of humanized immunoglobulins (i.e., containing non-native complementarity determining regions).

Reference A1 describes immunotoxins.

Respectfully submitted,

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LIST OF REFERENCES

CITED BY APPLICANT

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U.S. PATENT DOCUMENTS

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	AA	4,816,397	3/28/89	Boss et al.			
	AB	4,816,567	3/28/89	Cabilly et al.			

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	AF	W089/01783	3/9/89	PCT				
	AG	W086/05513	9/25/86	PCT				
	AH	W087/02671	5/7/87	PCT				
	AI	0,171,496	2/19/86	EPO				
	AJ	0,266,663	6/11/88	EPO				
	AK	2,188,941	10/14/87	GB				

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A1

Vitteta et al., "Redesigning Nature's Poisons to Create Anti-Tumor Reagents," Science 238:1098-1104 (1987).

A2

Ellison et al., "The nucleotide sequence of a human immunoglobulin C(gamma)1 gene", Nucleic Acids Res. 10:4071- (1982).

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A3		Hietzer et al., "Cloned Human and Mouse Kappa Immunoglobulin Constant and J Region Genes Conserve Homology in Functional Segments", Cell 22:197-207 (1980).
A4		Sharon et al., "Expression of a V <sub>H</sub> C <sub>H</sub> chimaeric protein in mouse myeloma cells", Nature 309:364-367 (1984).
A5		Takeda et al., "Construction of chimaeric processed immunoglobulin genes containing mouse variable and human constant region sequences", Nature 314:452-454 (1985).
A6		Tan et al., "A Human-Mouse Chimeric Immunoglobulin Gene with a Human Variable Region is Expressed in Mouse Myeloma Cells", J. Immunol. 135:3564-3567 (1985).
A7		Morrison et al., "Chimeric human antibody molecules: Mouse antigen-binding domains with human constant region domains", Proc. Natl. Acad. Sci. 81:6851-6859 (1984).
A8		Boulianne et al., "Production of functional chimeric mouse/human antibody", Nature 312:643-646 (1984).
A9		Neuberger et al., "A hapten-specific chimeric IgE antibody with human physiological effector function", Nature 314:268-270 (1985).
A10		Morrison, S.L., "Transfectomas Provide Novel Chimeric Antibodies", Science 229:1202-1207 (1985).

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| A11 | Sahagan et al., "A Genetically Engineered Murine/Human ChimERIC Antibody Retains Specificity for Human Tumor-Associated Antigen", J. Immunol. 137:1066-1074 (1986).                                 | <i>W</i> |
| A12 | Liu et al., "Expression of mouse:human immunoglobulin heavy-chain cDNA in lymphoid cells", Gene 54:33-40 (1987).  | <i>W</i> |
| A13 | Better et al., "Escherichia coli Secretion of an Active ChimERIC Antibody Fragment", Science 240:1041-1043 (1988).  | <i>W</i> |
| A14 | Waldmann, T.A., "The Structure, Function, and Expression of Interleukin-2 Receptors on Normal and Malignant Lymphocytes", Science 232:727-732 (1986).   | <i>W</i> |
| A15 | Leonard et al., "The human receptor for T-cell growth factor", J. Biol. Chem. 260:1872-1880 (1985).   | <i>W</i> |
| A16 | Uchiyama et al., "A monoclonal antibody (anti-Tac) reactive with activated and functionally mature human T-cells", J. Immunol. 126:1393-1397 (1981).  | <i>W</i> |
| A17 | Farrar, J., "The biochemistry, biology, and role of interleukin-2 in the induction of cytotoxic T cell and antibody-forming B cell receptors", Immunol. Rev. 63:129-166 (1982).                     | <i>W</i> |
| A18 | Greene et al., "Growth of Human T Lymphocytes: An Analysis of Interleukin 2 and Its Cellular receptor", in Progress in Hematology XIV, E. Brown, ed., Grune and Statton, New York (1986) p.283-301. | <i>W</i> |

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A19	Verhoyen et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity", Science 239:1534-1536 (1988).		
A20	Jones et al., "Replacing the complementarity-determining regions in a human antibody with those from a mouse", Nature 321:522-525 (1986).		
A21	Hale et al., "Remission Induction in Non-Hodgkin Lymphoma with Reshaped Human Monoclonal Antibody CAMPATH-1H", Lancet December 17, 1988, pp. 1394-1399.		
A22	Chothia, C. and A.M. Lesk, "Canonical Structures for the Hypervariable Regions of Immunoglobulins", J. Mol. Biol. 196:901-917 (1987).		
A23	Reichmann et al., "Reshaping human antibodies for therapy", Nature 332:323-327 (1988).		
A24	Bird et al., "Single-Chain Antigen-Binding Proteins", Science 242:423-426 (1988).		
A25	Huston et al., "Protein engineering of antibody binding sites: Recovery of specific activity in an anti-digoxin single-chain Fv analogue produced in Escherichia coli", Proc. Natl. Acad. Sci. U.S.A. 85:5879-5883 (1988). in Progress in Hematology XIV, E. Brown, ed., Grune and Station, New York (1986) p.283.		

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